

Remarks

Claims 1 - 14 are pending in the present application. Applicants thank the Examiner for the removal of objections to the claims and the 35 U.S.C. §112 rejections. The following rejections are at issue and are set forth by number in the order in which they are addressed:

1. Claims 1 - 4, 6 and 12 - 14 are rejected under 35 U.S.C. §102(b) as being anticipated by Allen-Hoffmann et al. (U.S. Pat. No. 5,989,837);
2. Claims 1 - 2, 4 - 9 and 12 - 13 are rejected under 35 U.S.C. §102(b) as being anticipated by Yang et al. (2000);
3. Claims 1 - 2 and 4 - 13 are rejected under 35 U.S.C. §103(a) as unpatentable over Yang et al. (2000);
4. Claims 1 - 4 and 6 - 14 are rejected under 35 U.S.C. §103(a) as unpatentable over Allen-Hoffmann et al. (U.S. Pat. No. 5,989,837); and
5. Claims 1 - 14 are rejected under 35 U.S.C. §103(a) as unpatentable over Yang et al. in view of Allen-Hoffmann et al. (U.S. Pat. No. 5,989,837).

Claim 1 has been amended in order to better clarify the claimed subject matter and to further Applicant's business interests and the prosecution of the present application in a manner consistent with the PTO's Patent Business Goals (PBG; 65 Fed. Reg. 54603 (September 8, 2000), and not in acquiescence to the Examiner's arguments and while reserving the right to prosecute the original (or similar) claims in the future. None of the claim amendments made herein are intended to narrow the scope of any of the amended claims within the meaning of *Festo Corp. v. Shokestu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 56 USPQ2d 1865 (Fed. Cir. 2000) or related cases. The amendments find more than ample support in the specification and the claims as originally filed. See, for example, page 39, lines 19 - 31.

1. The Claims are not Anticipated by Allen-Hoffmann et al.

Claims 1 - 4, 6 and 12 - 14 are rejected under 35 U.S.C. §102(b) as being anticipated by Allen-Hoffmann et al. (U.S. Pat. No. 5,989,837). The Federal Circuit has stated the relevant analysis for anticipation as follows:

A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference."

Verdegaal Bros. v. Union Oil Co. Of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicants have enclosed herewith the Declaration of Dr. Lynn Allen-Hoffmann, an inventor of the present invention as well as the invention claimed in the '837 patent. According to Dr. Allen-Hoffmann, the '837 patent does not teach maintaining the seeded dermal equivalent at the air interface until stratification occurs. In contrast, the '837 patent teaches submerging the seeded dermal equivalent for four days to allow the keratinocytes to adhere to the dermal equivalent as described at column 9, lines 27-51 and 18, line 54 - column 19, line 8 of the '837 patent. In particular, Allen-Hoffmann et al. states that "Cells were allowed to attach 2 hours before adding an additional 13 mls of media (Day 0). On days 1 and 2 cells were refed. On Day 4, cells were lifted to the air interface with cotton pads and switched to cornification medium . . ." As a result, Allen-Hoffmann et al. does not teach the claim element of maintaining the seeded dermal equivalent at the air interface. Accordingly, Applicants respectfully submit that this ground of rejection be removed and the claims passed to allowance.

2. The Claims are not Anticipated by Yang et al.

Claims 1 - 2, 4 - 9 and 12 - 13 are rejected under 35 U.S.C. §102(b) as being anticipated by Yang et al. (2000). On page 10, Yang et al. states that:

After the culture of dermal equivalent for 7 days, the culture medium was aspirated to leave the gel surface exposed, and epidermal keratinocytes were applied to the surface at an initial density of 1×10^5 cells/cm². The construct was submerged under keratinocyte culture medium inside and outside the of the culture insert to allow these keratinocytes to spread and cover the surface of the dermal equivalent, which is accomplished in approximately seven days of incubation.

Thus, the seeded dermal equivalent is resubmerged in medium for a substantial period of time. The Examiner has admitted this fact at page 5 of the office action. This is in contrast to the amended claims, which require maintaining the seeded dermal equivalent at the air interface until stratification occurs. As a result, Yang et al. does not teach each element of the pending claims. Furthermore, Applicants note that Yang et al. does not teach the incubation time elements of Claims 8 and 9. The Examiner failed to address this argument, which was made in applicant's previous response. Accordingly, Applicants respectfully submit that this ground of rejection be

removed and the claims passed to allowance.

3. The Claims are not Obvious over Yang et al.

Claims 1 - 2 and 4 - 13 are rejected under 35 U.S.C. §103(a) as unpatentable over Yang et al. (2000). A *prima facie* case of obviousness requires the Examiner to provide a reference(s) which (a) discloses all of the elements of the claimed invention, (b) suggests or motivates one skilled in the art to combine the claimed elements to produce the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of these three requirements precludes a finding of a *prima facie* case of obviousness and without more entitles the Applicants to allowance of the claims in issue. See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990). Applicants respectfully submit that the cited reference neither teaches nor suggests each element of the claims.

In particular, as described above, Yang et al. teaches submerging the seeded dermal equivalent in medium for a substantial period of time following seeding. The Examiner has admitted this fact at page 5 of the office action. This is in contrast to the amended claims, which require maintaining the seeded dermal equivalent at the air interface until stratification occurs. As a result, Yang et al. does not teach each element of the pending claims. Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness with respect to the pending claims. As such the claims should be passed to allowance.

4. The Claims are not Obvious over Allen-Hoffmann et al.

Claims 1 - 4 and 6 - 14 are rejected under 35 U.S.C. §103(a) as unpatentable over Allen-Hoffmann et al. (U.S. Pat. No. 5,989,837). The standards for making a *prima facie* case of obviousness are discussed above. As above, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness because the cited reference does not teach each element of the claims.

As above, Applicants respectfully direct the Examiner to the Declaration of Dr. Lynn Allen-Hoffman, an inventor of the present invention as well as the invention claimed in the '837 patent. According to Dr. Allen-Hoffman, the '837 patent does not teach maintaining the seeded

dermal equivalent at the air interface until stratification occurs. In contrast, the '837 patent teaches submerging the seeded dermal equivalent for four days to allow the keratinocytes to adhere to the dermal equivalent as described at column 9, lines 27-51 and 18, line 54 - column 19, line 8 of the '837 patent. In particular, Allen-Hoffmann et al. states that "Cells were allowed to attach 2 hours before adding an additional 13 mls of media (Day 0). On days 1 and 2 cells were refed. On Day 4, cells were lifted to the air interface with cotton pads and switched to cornification medium . . ." As a result, Allen-Hoffmann et al. does not teach the claim element of maintaining the seeded dermal equivalent at the air interface. Accordingly, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness with respect to the rejected claims. As such the claims should be passed to allowance.

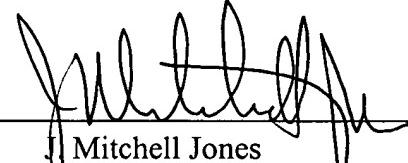
5. The Claims are not Obvious Over Yang et al. in view of Allen-Hoffman et al.

Claims 1 - 14 are rejected under 35 U.S.C. §103(a) as unpatentable over Yang et al. in view of Allen-Hoffmann et al. (U.S. Pat. No. 5,989,837). As can be seen from the discussion above, the cited references, either alone or in combination, fail to teach each element of amended claims, which require maintaining the seeded dermal equivalent at the air interface until stratification occurs. Accordingly, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness with respect to the rejected claims. As such the claims should be passed to allowance.

C O N C L U S I O N

All grounds of rejection and objection of the Office Action of January 13, 2004 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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